UNITED STATES DISTRICT COURT

DISTRICT OF NEW JERSEY

IN RE: VALSARTAN, LOSARTAN, AND IRBESARTAN PRODUCTS LIABILITY LITIGATION	**MDL No. 2875**
THIS DOCUMENT RELATES TO ALL CASES	**HON. ROBERT B. KUGLER CIVIL NO. 19-2875 (RBK)(KMW)**

PLAINTIFFS' REPLY BRIEF IN SUPPORT OF MOTION TO PRECLUDE THE OPINIONS OF DFENSE EXPERT LEE-JEN WEI, PH. D.

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INTRODUCTION

Defendants' Daubert Response demonstrates a misunderstanding of their burden of proof, as well as a misunderstanding of the key issues in this litigation. Defendants, not Plaintiffs, have the burden to demonstrate, by a preponderance of the evidence, the reliability of the scientific evidence they intend to offer. *See In re TMI Litig.*, 193 F.3d 613, 705 (3d Cir. 1999) ("it is the burden of the party offering the expert scientific testimony to demonstrate reliability by a preponderance of the evidence."). Defendants, however, spend much of their time trying to shift their burden to Plaintiffs.

Defendants' Brief is filled with broad, conclusory statements that have no discernible basis in law or fact. Defendants repeatedly defend Dr. Wei and his methodology, but are unable to provide any case law or substantive authority to support the position. These unsupported legal conclusions, as discussed in this brief, are not sufficient to demonstrate Dr. Wei survives *Daubert* scrutiny. Defendants' arguments therefore miss the mark, and because Defendants fail to offer sufficient support for the reliability of Dr. Wei's opinions, this Court should exclude Dr. Wei's causation opinions.

ARGUMENT

I. Defendants' Position Regarding Dr. Wei's Methodology Lacks Legal and Factual Support.

a. Dr. Wei's Methodology is Not Reliable

Dr. Wei's opinions should be excluded as his methodology is not reliable, because it is not generally supported by the scientific community. In this case, Dr. Wei applied subjective criteria when evaluating epidemiological studies relied on by Plaintiff expert Dr. Madigan. (See Plaintiff's Motion at 5-8). Rather than evaluating each study relied on by Plaintiffs' experts for

strengths and weaknesses, Dr. Wei arbitrarily excluded any study that did not contain a model fit assessment. Even though he was fully aware that this is not something that is commonly done (Wei Dep. (Day 1) 346:4-9; attached hereto as Ex. 1) and this is a very high standard to impose on observational studies, (Wei Dep. (Day 1) 349: 23- 350:12) Dr. Wei still applied this excessive, arbitrary standard to the literature that supports the Plaintiff's case, which is improper. *Player v. Montiva Enterprises LLC*, 166452, at *7 (D.N.J. January 20, 2006)(attached hereto as Exhibit 8).

Dr. Wei also erroneously concluded that the meta-analysis of observational studies that Plaintiffs relied on is not reliable because it was unclear whether the authors checked the adequacy of the model fit assessments utilized in underlying studies that were included in the meta-analysis. (Plaintiff's Motion at 8-10; Wei Report at 12 (attached hereto as Exhibit 2)). However, Dr. Wei admitted that meta-analyses of observational studies rarely check the adequacy of the model fit assessments utilized in underlying studies that are included in the meta-analyses. Further, he admitted that he was not aware of a single published meta-analysis that meets his demands. (Wei Dep. (Day 1) 374:17- 378:11). Dr. Wei argues that even though the vast majority of the scientific community publishes peer reviewed meta-analyses that do not meet his demands, he explains that we should not rely on these findings at all, because we should demand more of the scientific community. (Plaintiff's Motion at 9; (Wei Dep. (Day 1) 381:10-11). Of course, that is not a methodologically sound analysis.

Defendants incorrectly contend that because Dr. Wei applied his restrictive criteria to all of the studies cited by Plaintiffs, that Dr. Wei's methodology is reliable. (Def. Response at 11). This position misses the point of Plaintiff's argument, and falls short of the Daubert requirements. Rather than applying objective, generally accepted criteria (as he was supposed to have done),

Dr. Wei demands that Plaintiffs' literature meet his subjective requirements even though Dr. Wei admitted that this criteria is not commonly applied to the aforementioned body of literature, and he cannot provide a single example of a study that meets his unreasonably restrictive criteria. (Wei Dep. (Day 1) 374:17- 378:11). While it is imperative to assess the strengths and weaknesses of a study, Dr. Wei makes demands of observational studies that are rarely, if ever, met by the scientific community when publishing observational studies. Further, when Dr. Wei's demands are not met, he deems all of the observational studies "unreliable." (Wei. Dep. (Day 1) 349:23 – 350:6). No matter the case, Dr. Wei's subjective methodology would lead to exclusion of all or the vast majority of observational studies that are commonly relied upon by the scientific community. Therefore, Dr. Wei's methodology is unreliable and should be excluded. (See Plaintiff's Motion at 5-11).

b. Defendants Did Not Cite to A Single Source to Demonstrate Dr. Wei's Methodology is Reliable.

As Defendants stated in their Brief, "[i]n cases where a party objects to the admissibility to proffered expert opinion testimony, the court must examine qualifications, reliability, and fit. *R.D. v. Shohola, Inc.*, 2019 WL 6053223, at *3 (M.D. Pa. Nov. 15, 2019)(attached hereto as Exhibit 9)(citing *In re Paoli R.R. Yard PCB Litig.*, 35 F.3d 717, 741-47 (3d Cir. 1994) ("*Paoli II*")). Plaintiffs have objected to the admissibility of Dr. Wei's proffered expert testimony, so now the Court must examine his reliability. As the proponent of Dr. Wei's testimony, the burden is on the Defense to demonstrate that Dr. Wei meets the standards of 702. *See Magistrini v. One Hour Martinizing Dry Cleaning*, 180 F. Supp. 2d 584, 603 n.20 (D.N.J. 2002)("it is [the proponent's] burden, by a preponderance of the evidence, to show that his opinion is reliable and, in turn, that the basic underpinnings of his opinion are reliable. [The proponent] has not done so here."); *Pappas v. Sony Elecs., Inc.*, 136 F. Supp. 2d 413, 420 (W.D. Pa. 2000) ("The

proponent of the expert testimony bears the burden of showing that it satisfies the requirements of Rule 702.").

Contrary to the Defendants' argument, simply stating that "Dr. Wei's methodology is reliable" does not assist the Court in this inquiry. Rather, Defendants must actually demonstrate to the Court that Dr. Wei's methodology is reliable by demonstrating that it is, among other things, generally accepted in the scientific community. *Geiss v. Target Corp.*, 2013 WL 4675377 at 4-5* (D.N.J. 2013)(attached hereto as Exhibit 6). However, Defendants are unable to cite to one article, treatise, text book, or any other reputable source that demonstrates that Dr. Wei's unreasonably stringent methodology is considered to be reliable or utilized routinely in the scientific community. This is simply because such sources do not exist. Ironically, the only support Defendants provide to demonstrate that Dr. Wei's methodology is reliable is Dr. Wei's own testimony. (Def. Response at 10-11). The fact that Dr. Wei is the only source that supports Dr. Wei's methodology further reinforces Plaintiff's position that Dr. Wei is on an island of his own, and is applying a subjective criterion that is not recognized to be reliable in the scientific community.

Further, Defendants make numerous conclusory statements in an attempt to defend Dr. Wei's methodology that are, once again, not supported by any underlying facts or legal authority. For example, Defendants emphatically state that: "[a] less-commonly employed methodology does not render the methodology not generally accepted. This is particularly true here given the noted problems of observational studies, which are well known in the scientific community and long recognized by the courts." (Def. Response at 13). Defendants do not provide any legal authority to support these claims. Defendants do not explain any of the alleged "noted problems of observational studies," and they are unable to provide any examples of the aforementioned

"problems" being "well known in the scientific community and long recognized by the courts." This is not sufficient to rebut a *Daubert* challenge. These arguments, and the numerous similar arguments throughout Defendants' response, are unsubstantiated, and therefore, are unpersuasive to the question of whether Dr. Wei's are reliable. For the reasons stated above, Defendants have not adequately explained how Dr. Wei's exceptionally stringent evaluation of Plaintiffs' literature is reliable, or that it is accepted on any widespread basis, and therefore his expert opinion should be excluded.

c. Qualifications Are Not the Court's Only Consideration

Defendants also contend that Dr. Wei should not be excluded because he is well-qualified. (Def. Response at 18). However, an expert's qualifications are not the only factor considered in a *Daubert* evaluation. "Even if a witness is qualified as an expert regarding a particular issue, the process used by the witness in forming his expert opinion must be sufficiently reliable under *Daubert* and its progeny." *Salinero v. Johnson & Johnson,* 1:18-CV-23643-UU, 2019 WL 7753453, at *2 (S.D. Fla. Sept. 5, 2019)(attached hereto as Exhibit 10) (citing *Quiet Tech. DC-8, Inc. v. Hurel-Dubois UK Ltd.*, 326 F.3d 1333, 1342 (11th Cir. 2003) (stating that "one may be considered an expert but still offer unreliable testimony")). Dr. Wei may be generally qualified as a statistician, but the process he used to form his expert opinion regarding the aforementioned literature in this case is not sufficiently reliable, as it is not generally accepted in the scientific community. In addition, although the factors outlined in *Daubert* are not a "definitive checklist or test," *Daubert,* 509 U.S. at 593, 113 S.Ct. 2786, "when an expert is offering testimony that is presented as a *scientific* conclusion and the expert's method fails to satisfy *any* of the factors identified in *Daubert,* a court should pause and take a hard look before allowing a jury to consider it," *In re Mirena IUD Products Liab. Litig.,* 169 F. Supp. 3d 396, 430 (S.D.N.Y. 2016)

(citing *In re Methyl Tertiary Butyl Ether (MTBE) Prods. Liab. Litig.,* 593 F.Supp.2d 549, 564 (S.D.N.Y.2008) (emphasis in original). Here, Dr. Wei's methodology fails to satisfy the reliability factor of the *Daubert* analysis, therefore, whether he has the requisite qualifications or not, his entire opinion should be excluded.

II. Defendants Failed to Rebut that Dr. Wei's Opinions are Unreliable and Derived from Preconceived Notions

Dr. Wei's opinions are inherently unreliable as they were formed before his investigation began. Dr. Wei began his work on this case with the preconceived notion that the NDMA in Valsartan cannot cause cancer, and when he was presented with information to the contrary, he ignored or arbitrarily discounted it. (See Plaintiff's Motion at 6: Dr. Wei's rejection of NDMA dietary and occupational studies that demonstrate a link between NDMA and cancer).

Dr. Wei's preconceived notions explain why he copied and pasted large sections of his report, including sections that are not relevant to this litigation. (See Plaintiff's Motion at 14-15). This also explains why Dr. Wei criticizes Dr. Madigan's Lifetime Cumulative Exposure (LCE) calculations, despite having no knowledge of key, but very simple pieces of information needed to conduct such calculations. (See Plaintiff's Motion at 15-19). Finally, it is the only explanation as to why Dr. Wei would confidently claim the NDMA in Valsartan is not significant enough to cause cancer without having any idea how much NDMA was detected in Valsartan. (See Plaintiff' Motion at 19-20). While such serious preconceived notions would certainly lend themselves to credibility issues that can be addressed on cross-examination as Defendants contend, here however, they are so central to Dr. Wei's opinions, that they undermine the reliability of his methodology entirely. Dr. Wei's formation of his opinions before his analysis turns the scientific process required by our Courts on its head, and therefore, his opinions should be excluded. *Chester Valley Coach Works v. Fisher-Price, Inc.,* 2001 WL 1160012 1, *4 (E.D.

Pa. Aug. 29, 2001)(holding that "[a]n expert should not approach an investigation with preconceived notions of results.")(attached hereto as Exhibit 5).

a. Dr. Wei's Copied-and-Pasted Report Further Highlights the Unreliability of His Opinions

Dr. Wei copied and pasted numerous pages of his report from prior expert reports that he wrote up to 15 years ago. (See Plaintiff's Motion at 12-13). Plaintiffs will briefly address the case law cited by Defendants, as this is one of the few issues for which Defendants cited any authority to support their arguments. Defendants cite *Salinero v. Johnson & Johnson*, 2019 WL 7753453 (S.D. Fla. Sept. 5, 2019), in which a doctor who copied his current report from a report submitted in other litigations was not excluded. Defendants claim, "the same reasoning applies here." However, contrary to Defendants unsupported position, this case is distinguishable from the present case. In *Salinero*, the doctor in question incorporated sections of previous reports that he drafted in other mesh litigations, which involved generally the same product that was at issue in the 2019 litigation. In this case, Dr. Wei applied his time-honored template that he has compiled over the last fifteen years. He copied significant sections of his report from reports he submitted in other litigations that have nothing to do with Valsartan, cancer, clinical studies, nitrosamines, NDEA, or NDMA. The only common threads amongst all of Dr. Wei's reports are that he wrote them on behalf of a corporate defendant, and he found no statistical significance to support the plaintiff's allegations, just as he did in this case. (See Plaintiff's Motion at 12-14; Dr. Wei's report submitted in *In re Taxotere Products Liability Litigation* (2019) (attached here to Exhibit 3); Dr. Wei's report submitted in *In re Bextra and Celebrex Marketing, Sales Practices and Products Liability Litigation* (2007) (Attached hereto as Exhibit 4)). That is his preconceived plan, and he executed it here as well. Dr. Wei started this litigation with a conclusion in mind, and applied subjective methodology in order to reach that conclusion, which

renders his opinion unreliable. *Chester Valley Coach Works v. Fisher-Price, Inc.,* 2001 WL 1160012 1, *4 (E.D. Pa. Aug. 29, 2001)(holding that "[a]n expert should not approach an investigation with preconceived notions of results*."); In re Diet Drugs*, MDL 1203, 2001 WL 454586 1, *14 (E.D. Pa. Feb. 1, 2001) (starting with assumptions about the findings and attempting to confirm the assumption inverts scientific method, which further undermined the reliability of the expert who applied a subjective methodology)(attached hereto as Exhibit 7)); *Caraker v. Sandoz Pharm. Corp.,* 172 F. Supp. 2d 1018, 1049, fn. 5 (S.D. Ill. 2001) ("Justifying a conclusion after the fact by applying a methodology does not generally lead to reliable scientific knowledge."); *In re Mirena IUD Levonorgestrel-Related Prods. Liab. Litig. (No. II)* 341 F. Supp. 3d 213, 241 (S.D.N.Y. 2018) (holding, "[M]ethodology …. aimed at achieving one result … is unreliable, and … must be excluded" (quoting *Faulkner v. Arista Records LLC,* 46 F. Supp. 3d 365, 381 (S.D.N.Y. 2014)). This approach to drafting an expert report is the epitome of results-driven and "does not rise to the level of intellectual rigor employed in the medical or scientific field." *In re Mirena*, 169 F. Supp. 3d 396, 430 (S.D.N.Y. 2016).

b. Defendants Misrepresent the Significance of Dr. Wei's Use of a Recycled Report

Defendants also claim Dr. Wei is permitted to copy and paste sections of his report because "Plaintiffs' experts do the same." (Def. Response at 17.) Defendants fail to provide any example of Plaintiffs' experts copy and pasting sections of their reports. Additionally, Defendants grossly understate the severity of Dr. Wei's reuse of previous reports. To be clear, if Dr. Wei copied a limited part of a prior report that directly applied to this case, or generic portions of other reports that were not substantive, Plaintiffs would not have raised this issue. However, Dr. Wei, as discussed in the motion to exclude his opinions, copied roughly thirty percent of his report from reports submitted in previous litigations. (See Plaintiff's Motion at 13;

(Wei Dep. (Day 1) 98-112; 118- 124; 173-209)). His opinion is based on preconceived notions, which demonstrates that his opinion is unreliable, and should be excluded.

III. Defendant's Argument to Rebut Dr. Wei's Lack of Knowledge Regarding Toxicology Measurements, Lifetime Cumulative Exposure and Amount of NDMA in VCDs Lacks Merit

For the reasons stated in Plaintiff's Initial Motion, and additional arguments below, Dr. Wei simply lacks the requisite knowledge to discuss the carcinogenicity of NDMA, and any such opinions should be excluded from his report. (Plaintiff's Motion at 19-20) (Wei Deposition (Day 1) at 275:7 - 276:6)). In Plaintiff's initial motion to exclude Dr. Wei, Plaintiffs asked this Court to exclude Dr. Wei's opinion regarding the carcinogenicity of NDMA, because he knows very little about the levels of NDMA in the studies cited by Plaintiffs, and has no knowledge of the levels of NDMA in Valsartan. (Plaintiff's Motion at 19-20). Specifically, Plaintiff's asked to exclude any testimony pertaining to his opinion that "using the results from non-valsartan studies to claim issues for potential carcinogenicity *of low levels of an NDMA impurity* in valsartan is not scientifically valid" (Wei Report at 15)(Plaintiff's Motion at 19), as that is not a valid position.

In response, the defense did not directly explain any of the factual issues raised by Plaintiffs. Instead, Defendants mischaracterized evidence that supports excluding Dr. Wei. Defense claims that during Dr. Wei's deposition, he simply "fail[ed] to remember" certain abbreviations, as well as the amount of NDMA in Valsartan, which, according to them, does not create a ground to exclude his testimony. (Def. Response at 17-18). If this were truly an issue pertaining to the doctor's faulty memory, then Defendants may be correct. However, as demonstrated by the deposition transcript, Dr. Wei did not simply "forget" critical information such as the amount of NDMA in Valsartan. Rather, he never knew it at all. This is made clear numerous times in his deposition testimony:

Q. Doctor, I want to ask you about the levels of NDMA that were found in valsartan, okay?

A. Yes, sir.

Q. **Do you know what the levels of NDMA were that were found in valsartan?**

A. **I don't know,** sir.

Q. Do you have any way of describing the levels of NDMA that were found in valsartan?

A. **No,** sir.

Q. Do you have any idea or any way of describing how long the valsartan medications were contaminated for in the U.S.?

A**. No, sir**.[1]

Dr. Wei does not state he cannot recall this information. He did not say he forgot this information. Rather he stated, numerous times, that he "does not know" the amount of NDMA in Valsartan. Further, Dr. Wei clearly stated that he never reviewed key documents (which were also cited by Plaintiff's Experts) that would have provided him with this information:

Q. Do you recall reviewing either of those two documents?

A. No. I didn't read the spreadsheet of NDMA. Actually don't.

Q. You don't recall ever laying eyes on the spreadsheet of "NDMA Test Results For ZHP API" or the Torrent Pharmaceuticals Limited document, correct?

A. Yeah, I know they sent it to me, but I notice that Dr. Madigan didn't even mention anything, **so I didn't read it.**

Q. Okay. And I'm sorry. Is it your testimony that Dr. Madigan never mentioned anything about test results?

A. Well, he didn't mention this spreadsheet citing this document. **So I didn't read it**.

[1] Wei Deposition (Day 1) at 275:7 - 276:6.

Q. It's your testimony both the spreadsheets of "NDMA Test Results For ZHP API" and the "Torrent Pharmaceutical Limited Valsartan Impact Assessment of NDMA," that Dr. Madigan didn't review those so **you didn't review them either; is that correct?**

A. **That's my recollection**…[2]

Based on the testimony above, and other excerpts like them, it is disingenuous for Defense to tell this Court that Dr. Wei simply "forgot" critical information pertaining to the amount of NDMA in Valsartan. Dr. Wei admits that he never reviewed that information, and does not currently know that information. Therefore, this is not just a credibility issue reserved for cross-examination, as Defendants claim. (Def. Response at 18). This issue is much more significant than that: The level of NDMA in Valsartan is directly relevant to this case, and documents that provide these levels tends to rebut Dr. Wei's opinion, but he did not acknowledge or account for these documents. His failure to review or consider these documents warrants exclusion on his opinions. *In re Zoloft Products Liability Litigation,* 176 F. Supp. 3d 449, 460-61 (E.D. Pa. 2016) (holding "[I]f the relevant scientific literature contains evidence tending to refute the expert's theory and the expert does not acknowledge or account for that evidence, the expert's opinion is unreliable.') citing *In re Rezulin Products Liability Litigation,* 369 F. Supp. 2d 398, 425 (S.D.N.Y. 2005), emphasis added.

Dr. Wei's lack of knowledge regarding perhaps one of the most important facts in this litigation directly demonstrates his lack of effort in investigating his client's position in this case, and further highlights his preconceived notions that led to his ultimate conclusion. Dr. Wei had numerous opportunities to learn this information prior to drafting his report and sitting for his deposition. Although several documents that contained the levels of NDMA in Valsartan were

[2] Wei Dep. (Day 2) 87:10 – 88:15.

cited by Plaintiffs' Experts, including Dr. Madigan, were provided to Dr. Wei by Defense counsel, and were listed on Dr. Wei's Materials Considered List, it is abundantly clear Dr. Wei never laid eyes on them. He did not need to in order to support his predetermined opinion.

Since Dr. Wei does not know the amount of NDMA in Valsartan, he cannot opine that the amount of NDMA in Valsartan does not present a risk of carcinogenicity. Dr. Wei does not even possess the knowledge to opine that the levels in Valsartan are "low," or any synonym thereof. Since Dr. Wei lacks the factual knowledge necessary to opine on the amount of NDMA in Valsartan, as well as knowledge of the amount of NDMA in literature he criticizes, he should also be precluded from testifying that the results from "non-valsartan studies" are not sufficient to demonstrate a risk of carcinogenicity related to Valsartan, as he has done in his report. (Wei Report at 15). This Court should not allow Dr. Wei to offer any opinions regarding an area in which he has no expertise, and for the reasons explained above, should exclude all of his opinions regarding the carcinogenicity of NDMA.

CONCLUSION

Defendants fail to offer adequate evidence that Dr. Wei's opinion and scientific method are reliable. Accordingly, and for the additional reasons stated in the Plaintiff's motion, this Court should GRANT Plaintiff's motion to exclude all of Dr. Wei's opinions on general causation.

Respectfully,

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Dated: January 6, 2022

CERTIFICATE OF SERVICE

I hereby certify that on January 6, 2022, I electronically filed the foregoing document with the Clerk of the Court using the CM/ECF system which will send notifications of such filing to the CM/ECF participants registered to receive service in this MDL.

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